



April 24, 2025

**National Stock Exchange of India Limited**

Exchange Plaza,  
Bandra Kurla Complex,  
Bandra (East),  
Mumbai - 400 051

**Symbol: LUPIN**

**BSE Limited**

P. J. Towers, Dalal Street,  
Mumbai Samachar Marg,  
Mumbai - 400 001

**Scrip Code: Equity - 500257**

**Subject: Disclosure pursuant to Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ('Listing Regulations').**

*Dear Sir/Madam,*

We are pleased to enclose a Press Release as regards, receipt of approval from the U.S. FDA for the Company's Abbreviated New Drug Application for Tolvaptan Tablets, 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg, which are the bioequivalent to Jynarque® Tablets, 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg, of Otsuka Pharmaceutical Company Ltd.

The same is for your information and dissemination.

Thanking you,

**For LUPIN LIMITED**

**AMIT KUMAR GUPTA  
COMPANY SECRETARY & COMPLIANCE OFFICER  
(ACS -15754)**

**Encl: a/a.**

LUPIN LIMITED

**Registered Office:** 3<sup>rd</sup> Floor, Kalpataru Inspire, Off W. E. Highway, Santacruz (East), Mumbai - 400 055 India. Tel: (91-22) 6640 2323.

Corporate Identity Number: L24100MH1983PLC029442

[www.lupin.com](http://www.lupin.com)

## Lupin Receives Approval from U.S. FDA for Tolvaptan Tablets

Being the exclusive first-to-file, Lupin is eligible for 180-day generic exclusivity

**Mumbai, Naples, April 24, 2025:** Global pharma major Lupin Limited (Lupin) today announced that it has received approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Tolvaptan Tablets, 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg. Tolvaptan Tablets are bioequivalent to Jynarque® Tablets, 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg, of Otsuka Pharmaceutical Company, Ltd. Lupin is the exclusive first-to-file for this product and is eligible for 180 days of generic drug exclusivity. This product will be manufactured at Lupin's Nagpur facility in India and will be launched soon.

Tolvaptan is indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

“We are very pleased to have obtained approval for generic Tolvaptan from the U.S. FDA. This marks a significant entry into the nephrology segment and demonstrates our commitment to addressing the unmet needs of patients globally,” said **Vinita Gupta, CEO, Lupin**.

Tolvaptan Tablets (RLD Jynarque®) had an estimated annual sale of USD 1,467 million in the U.S. (fiscal year ended December 31, 2024).

### About Lupin

Lupin Limited is a global pharmaceutical leader headquartered in Mumbai, India, with products distributed in over 100 markets. Lupin specializes in pharmaceutical products, including branded and generic formulations, complex generics, biotechnology products, and active pharmaceutical ingredients. Trusted by healthcare professionals and consumers globally, the company enjoys a strong position in India and the U.S. across multiple therapy areas, including respiratory, cardiovascular, anti-diabetic, anti-infective, gastrointestinal, central nervous system, and women's health. Lupin has 15 state-of-the-art manufacturing sites and 7 research centers globally, along with a dedicated workforce of over 23,000 professionals. Lupin is committed to improving patient health outcomes through its subsidiaries - Lupin Diagnostics, Lupin Digital Health, and Lupin Manufacturing Solutions.

To know more, visit [www.lupin.com](http://www.lupin.com) or follow us on LinkedIn <https://www.linkedin.com/company/lupin>

For further information or queries please contact:

**Rajalakshmi Azariah**

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Jynarque® is the registered trademark of Otsuka Pharmaceutical Company Ltd.